

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO**

IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION

MDL NO. 2804

Civ. No. 1:17-md-02804-DAP

THIS DOCUMENT RELATES TO:
Track One Cases

JUDGE POLSTER

**AMERISOURCEBERGEN CORPORATION AND
AMERISOURCEBERGEN DRUG CORPORATION'S TRIAL BRIEF**

Pursuant to the Civil Jury Trial Order (ECF No. 1598), Defendants AmerisourceBergen Drug Corporation ("ABDC") and AmerisourceBergen Corporation ("ABC") hereby submits this Trial Brief for the October 21, 2019 Track One Trial in the above-captioned matter. ABDC and ABC specifically reserve the right to amend, supplement, or otherwise modify any of the positions set forth in this Trial Brief, in advance of or during trial, including based on the presentation of evidence by Plaintiffs or any other Defendants.

I. Statement of the Facts

ABDC is a wholesale distributor of prescription medications, including controlled substances. The controlled substances ABDC distributes include prescription opioid products. In addition to prescription medications, ABDC distributes a wide variety of products, including over the counter medications and health and beauty aids; opioid products make up only a very small percentage of the products distributed by ABDC. ABDC distributes pharmaceutical products to customers around the country, including to hospitals, retail and independent pharmacies, long-term care facilities, hospice providers, the Department of Defense, and others. ABDC's customers in Cuyahoga County include the Cleveland Clinic and other health systems. Consistent with federal

and state regulations, ABDC distributes to customers only to the extent that those customers are registered with the DEA and licensed in their specific state.

As a wholesale distributor of prescription medications, ABDC has a limited role in the healthcare supply chain. ABDC does not and cannot control how medications that it distributes are prescribed, dispensed, or ultimately used. Nor does ABDC promote the prescribing or use of medications, including opioids, to doctors or patients, or determine the appropriate supply of opioids.

ABDC has always complied with its requirements under the Controlled Substances Act (“CSA”), including: (1) the requirement to maintain effective controls against diversion of controlled substances and (2) the requirement to report suspicious orders of controlled substances to the DEA. ABDC also reports all transactions of controlled substances to the DEA on a daily basis through the DEA’s ARCOS system.

ABDC’s history of compliance with the CSA dates back into (and past) the 1990s. Indeed, from 1996 to 1998, ABDC’s predecessor, Bergen Brunswig, developed a new computer-based suspicious order monitoring system, in coordination with the DEA. Bergen Brunswig’s program was approved by the DEA, in writing, in 1998. This program involved reporting suspicious orders to the DEA after they were shipped, which the DEA knew when it approved the program. ABDC operated its DEA-approved program until 2007.

On April 19, 2007, DEA issued an Order to Show Cause and Immediate Suspension of Registration (“ISO”) for ABDC’s Orlando, FL distribution center, alleging that the Distribution Center had failed to maintain effective controls against diversion. The ISO did not focus on whether ABDC had shipped suspicious orders; instead, the ISO focused on volume distributed to certain specified pharmacies (all four of which were either located in Florida or were internet

pharmacies) and customer due diligence processes. The ISO did not contain any allegations related to any customers or distribution of controlled substances in Ohio.

Between April and June 2007, ABDC and DEA worked hand-in-hand developing a new system to detect and report suspicious orders. On June 22, 2007, ABDC and DEA entered into a Settlement and Release Agreement in which ABDC “agree[d] to maintain a compliance program designed to detect and prevent diversion of controlled substances.” The Agreement did not include any financial penalty or fine, and stated that it was not “an admission of liability by [ABDC]” and “[ABDC] expressly denies the DEA’s allegations.”

ABDC’s new diversion control program had three pillars: (1) new customer due diligence; (2) an order monitoring program that flagged orders of interest and were reviewed by a trained diversion control team member; and (3) ongoing customer due diligence. Following DEA functional compliance reviews of the new system, DEA dissolved the ISO on August 25, 2007. Under this new program, and from 2007 through present day, ABDC does not ship orders it reports as suspicious to DEA.

ABDC again undertook to further enhance its program in 2015. ABDC’s current program has the same three pillars: (1) new customer due diligence; (2) an order monitoring program that flagged orders of interest and were reviewed by a trained diversion control team member; and (3) ongoing customer due diligence. Supported by an outside data analytics consultant, ABDC’s program also includes sophisticated analytics and software that further support both order monitoring and customer due diligence.

II. Controlling Law

Consistent with direction provided by Special Master Cohen, ABDC and ABC incorporate by reference the legal positions set forth in previously filed Motions to Dismiss and Motions for

Summary Judgment, including, but not limited to, the following submissions (including related briefing):

- Defendants AmerisourceBergen Drug Corp., Cardinal Health, Inc., and McKesson Corp.'s Motion to Dismiss (Fed. R. Civ. P. 12(B)(6)) (ECF No. 491);
- Distributor Defendants' Motion for Summary Judgment on Plaintiffs' Negligence Per Se Claims (ECF No. 1861);
- Motion for Summary Judgment on Preemption by Pharmacy Defendants, ABDC, Cardinal, and McKesson (ECF No. 1883);
- Distributors and Manufacturers Motion for Partial Summary Judgment on Statute of Limitations Grounds (ECF 1896);
- Distributor Defendants' Motion for Summary Judgment on Civil Conspiracy Claim (ECF No. 1908);
- Distributor Defendants' Motion for Summary Judgment on Proximate Causation Grounds (ECF No. 1920); and
- Distributor Defendants' Motion for Summary Judgment on Plaintiffs' RICO and OCPA Claims (ECF No. 1921).

At trial, ABDC and ABC anticipate that the most pertinent legal questions will turn on: (1) the elements for the causes of action asserted by Plaintiffs; (2) the elements for the defenses asserted by Defendants;¹ and (3) issues related to non-party fault and contribution, including as to non-parties, severed and/or settled parties, and Plaintiffs. Because Plaintiffs have not provided adequate notice as to how they intend to try their case in chief (including through serious overbreath in their exhibit list, witness list, and deposition designations), ABDC and ABC are not presently able to identify all legal issues that may arise at trial with greater precision. Further, additional legal questions may be relevant at trial depending on the Court's rulings on the Defendants' Motions in Limine.

¹ ABDC and ABC incorporate by reference their Affirmative Defenses as set forth in ABDC's Answer to Plaintiffs' Corrected Second Amended Complaint with Affirmative Defenses (ECF No. 1251).

III. Evidentiary Issues Likely to Arise at Trial

Consistent with direction provided by Special Master Cohen, ABDC and ABC incorporate by reference the legal positions set forth in the Motions in Limine filed by the Defendants on September 25, 2019. ABDC and ABC also anticipate that Plaintiffs will file Motions in Limine, and ABDC and ABC incorporate by reference any future responsive briefing on Plaintiffs' Motions.

ABDC and ABC further state that evidentiary issues will likely arise related to: the admissibility of witness testimony and documentary evidence, including related to Plaintiffs' proffered expert witnesses; the presentation of Plaintiffs' case-in-chief against ABDC and ABC; and ABDC and ABC's defenses, including, but not limited to: that ABDC and ABC have complied with all relevant laws and regulations and have not engaged in any tortious or otherwise improper conduct; Plaintiffs' inability to prove that any conduct by ABDC or ABC caused any harm to them; and the fact that Plaintiffs' claims are untimely. Evidentiary issues will also likely arise related to the issue of non-party fault and contribution, including as to non-parties, severed and/or settled parties, and Plaintiffs. Because Plaintiffs have not provided adequate notice as to how they intend to try their case in chief (including through serious over-breath in their exhibit list, witness list, and deposition designations), ABDC and ABC are not presently able to identify the evidentiary issues that may arise at trial with greater precision

Dated: September 25, 2019

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CERTIFICATE OF SERVICE

I, Robert A. Nicholas, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

/s/ Robert A. Nicholas
Robert A. Nicholas